

Appl. No. 10/713,043
Amtd. dated September 14, 2006
Reply to Office action of June 15, 2006
Atty. Docket No. AP818US/CIP

RECEIVED
CENTRAL FAX CENTER

REMARKS/ARGUMENTS

SEP 14 2006

Paragraph 12 of the Office Action Summary makes no mention of the certified copy of the priority document supporting the claim to foreign priority under 35 U.S.C. § 119. Applicant requests, for the record, acknowledgement that the certified copy was received in connection with parent application number 09/978,595 (now patent number 6,650,930).

In paragraph 2 of the office action, claims 1-4, 6-16 and 18-26 were rejected on the ground of non-statutory obviousness-type double-patenting over claims 1-21 of United States patent number 6,650,930 (Ding). The present application is a Continuation-in-Part of application number 09/978,595 (now US 6,650,930) and is commonly owned therewith. Accordingly, the rejection has been overcome by means of a terminal disclaimer which is submitted herewith on Form PTO/SB/26.

In paragraph 4 of the office action, claims 1-26 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Publication No. 2003/0139700 (Elliott *et al.*) This rejection is respectfully traversed on the grounds that the examiner has not established a proper *prime facie* case of obviousness. (In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); In re Bell, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993)).

In paragraph 5 of the office action, the examiner stated that "Elliott *et al.* discloses" and then went on to list a number of items that allegedly were disclosed. The examiner did not mention any elements of the claims that are absent from Elliott *et al.*'s disclosure, and which a skilled addressee would be motivated to add, and did not mention any elements which a skilled addressee might be motivated to modify or substitute. Consequently, it is not clear whether the examiner correctly rejected the claims under 35 U.S.C. 103(a) but failed to make out a proper case of obviousness, or really intended to reject the claims as anticipated under 35 U.S.C. 102. In the circumstances, the rejection of claims 1-8, 11-20 and 23-26 should be withdrawn.

Notwithstanding that, and with a view to expediting examination, the Elliott *et al.* disclosure has been considered to determine whether it would support either ground of rejection, viz. anticipation or obviousness. It has been concluded that it cannot, for the reasons set out below.

Firstly, Elliott *et al.*'s disclosure is not analogous art (M.P.E.P. 2141.01(a)). Elliott *et al.* disclose a user interface for an automated system for loading a series of low dose radioisotope seeds into each of an array of implant needles for subsequent use in brachytherapy or the like. (Para. [0002]). According to Elliott *et al.*, an array of the implant needles are used to inject the seeds to form a grid of isotopes in the patient. (Para [0003]). Allegedly, Elliott *et al.*'s automated system addresses problems associated with manual insertion or loading of the radioactive seeds into the implant needles prior to their injection into the patient. It does so by

Appl. No. 10/713,043
Amdt. dated September 14, 2006
Reply to Office action of June 15, 2006
Atty. Docket No. AP818US/CTP

automatically loading seeds from a cartridge into each implant needle. This operation takes place before the radiotherapy (brachytherapy) session.

In contrast, the present invention relates to dosimetry, i.e., the measurement of radiation doses actually received by the patient ("body" or "body part") during the radiotherapy session and specifically to the creation of a report after the irradiation takes place. The present invention addresses disadvantages of known dosimetry systems, namely that "it is not easy to confirm that the dose values measured were taken at the proper locations on the body of the patient" (Page 2, lines 6, 7). It does so by creating a report which contains a representation of the body or body part, graphics artefacts (icons) representing the radiation sensors used during the radiotherapy and a listing of actual radiation doses measured by the sensors.

A person seeking a solution to the problems associated with confirming that the "dose levels were taken at the proper locations on the body of the patient" would not be motivated to look to such a radioisotope seed loading system for guidance. (*In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986); *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979). Accordingly, the rejection of claims 1-8, 11-20 and 23-26 should be withdrawn.

Secondly, notwithstanding the foregoing, even if the skilled addressee were aware of the Elliott *et al.* disclosure, it would not lead him to the present invention. With italics added for emphasis, claim 1 of the present application reads as follows:

1. A method of producing a radiation dosimetry report containing radiation doses, each corresponding to a respective one of a plurality of radiation sensors positioned in, on or adjacent a body or a body part during irradiation thereof, the method comprising the steps of:-
 - (i) providing a *representation comprising an image of at least a portion of the body or body part that has been irradiated* and arranging a plurality of *graphics artefacts on or adjacent the representation*, each artefact comprising an identifier and representing a radiation sensor positioned in, on or adjacent the body or part thereof during irradiation, the position of each artefact relative to the representation corresponding to the position of a corresponding sensor relative to the body during irradiation; and
 - (i) listing radiation doses associated with the plurality of identifiers, respectively.

As explained above, the present invention is concerned with accurate reporting of radiation dose levels at particular points on a body, such as that of a person, during radiation therapy. A difficulty experienced with known radiation monitoring systems is that they produce

Appl. No. 10/713,043
Amdt. dated September 14, 2006
Reply to Office action of June 15, 2006
Atty. Docket No. AP818US/CIP

reports which require interpretation by the physician who wishes to determine what parts of the body received what radiation dose. The present invention addresses that difficulty by providing a dosimetry report which includes (i) a representation, for example a line drawing, regular photograph, X-ray photograph, and so on, of the body or body part which has been irradiated; (ii) a set of graphics artefacts which show where the radiation sensors were positioned during the irradiation process; and (iii) a listing of the actual radiation doses measured by the respective sensors and, hence, at the different positions on the patient's body. Such a dosimetry report enables the physician to see immediately whether the correct amount of radiation was received by a particular part of the patient's body. Advantageously, there is no need to interpolate information from two different reports or displays in order to determine the physical location at which a particular dose was measured, which not only saves time but reduces the risk of error.

The discussion of Elliott *et al.* in paragraph 5 of the office action suggests that the examiner has not appreciated the distinction between a dosimetry system, which measures radiation doses received from radiation sources during a radiotherapy session, and a system for loading radiation sources in the form of radioactive seeds into an array of implant needles, before the seeds are implanted and the needles withdrawn. In so far as Elliott *et al.* measure radiation, it is of the seeds before they are implanted into the patient (for example, the prostate gland).

Thus, Elliott *et al.*'s display shows the positions of implant needles within a loading pattern grid. In particular, Elliott *et al.* discloses "a user interface that displays information about the automated system and accepts commands from a user to control the process of ejecting the radioisotope seeds into the implant needles. The user interface allows a user to alter a predetermined dose plan during the process of loading the implant needles. Preferably, the user interface is a touch-screen interface that displays a graphic representation of the coordinates of a plurality of locations, with the user selecting the next location by touching one of the coordinates". (Emphasis added) (Abstract; Para. [0015]; claim 4 *et al.*). Also, Elliott *et al.*'s paragraph [0063] states "The System Setting button 204 allows the user to view and edit various parameters of the automated system 10, including radiation measurement parameters, radiation calibration settings, motion control parameters and display preferences. In the case of radiation measurement parameters, the user is preferably given the option in a set-up window of choosing to monitor (i) all contents, (ii) all seeds, (iii) every given number of seeds, or (iv) only the first seed in each implant needle". Thus, Elliott *et al.* are interested in the seeds themselves.

Moreover, although Elliott *et al.*'s system can generate reports, they are not reports of actual doses received by the patient during therapy and do not use a representation of the body or body part being irradiated. Also, although Elliott *et al.* mention the option of obtaining an ultrasound image of the body part (Para. [0079]), it is in the context of dose planning by the physician and the image is not used to show where specific doses were received during the therapy session.

Appl. No. 10/713,043
Amtd. dated September 14, 2006
Reply to Office action of June 15, 2006
Atty. Docket No. AP818US/CIP

Since Elliott *et al.*'s disclosure neither discloses nor suggests the features of applicant's claim 1, and the examiner's interpretation of applicant's claim 1 and Elliott *et al.*'s disclosure is incorrect, a *prima facie* case of obviousness of claim 1 has not been properly established. Accordingly, it is respectfully requested that the rejection of claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Each of claims 2 to 12 is dependent directly or indirectly upon claim 1 and so includes all of its features. Accordingly, the rejection of claims 2 to 12 should be withdrawn for the same reasons as for claim 1.

Independent claim 13 is directed to a dosimetry report having novel features corresponding to those of claim 1, including the representation of the body or body part. Consequently, claim 13 is patentable over the Elliott *et al.* disclosure for the same reasons as claim 1, and the rejection of claim 13 should be withdrawn. Each of claims 14 to 24 is dependent directly or indirectly upon claim 13 and so includes all of its features. Accordingly, the rejection of claims 14 to 24 should be withdrawn for the same reasons as for claim 1.

Independent claim 25 is directed to a dosimetry report comprising a photograph of at least a portion of a body that was irradiated, with a plurality of sensors positioned in, on or adjacent the body or portion thereof, together with dosimetry data. Elliott *et al.* neither disclose nor suggest such a dosimetry report employing a photograph. Accordingly, the examiner has failed to establish a proper *prima facie* case of obviousness and the rejection of claim 25 should be withdrawn. Claim 26 is dependent upon claim 25 and so includes all of its features. It follows that it is patentable over the Elliott *et al.* disclosure for the same reasons as claim 25. In addition, claim 26 specifies that the dosimetry data is displayed as a list of radiation doses associated with the sensors, i.e., the sensors shown in the photograph, which is neither disclosed nor suggested by Elliott *et al.*

In view of the foregoing, it is submitted that all claims of record are patentable over the cited references and the applicant respectfully requests withdrawal of the rejection of claims 1 - 26 and early and favourable reconsideration and allowance of the application.

With a view to expediting allowance, the examiner is invited to call the undersigned at (613) 254 9111 if she has any further concerns.

Respectfully submitted,



Thomas Adams, Reg. No. 31,078